

The meeting was called to order by Heather Fukushima at 8:30 a.m. The following members were present via telephone:

- Emily Putnam-Hornstein, University of Southern California
- Sun Lee, Los Angeles County Department of Public Health
- Linda Remy, University of California, San Francisco
- Ninez Ponce, University of California, Los Angeles

California Department of Public Health staff present:

- Ellen Badley, Branch Chief
- Michelle Miles, Section Chief
- Jennifer Rico, Science Advisor
- Laura Lund, Science Advisor
- Sandra Bannerman, Unit Chief
- Heather Fukushima, Specialist
- Steven Hoang, Analyst

Public Attendees present at the meeting:

- None

Public Attendees present via telephone:

- None

INTRODUCTIONS AND ANNOUNCEMENTS

Ms. Fukushima informed those present that the meeting was being recorded to assist with note-taking purposes, and that the meeting complied with the Bagley-Keene Open Meeting Act.

Public attendees were asked to reserve any comments until the Public Comments portion of the meeting.

APPROVAL OF MINUTES FROM PREVIOUS MEETING

A **MOTION** was made by Sun Lee and **SECONDED** by Ninez Ponce to approve the December 14, 2016 meeting minutes. Sun Lee, Emily Putnam-Hornstein, and Ninez Ponce voted aye to approve the previous meeting's

minutes as distributed. Linda Remy abstained from voting as she had not attended the previous meeting.

ATTACHMENT 1 – STATE REGISTRAR’S RESPONSE TO VSAC RECOMMENDATIONS

The State Registrar adopted twelve of the eighteen items listed in Attachment 1.

Five applications listed were not heard (the Science Advisor had determined that two did not require VSAC review, and three applications were not reviewed due to the need for additional information requested from the applicants). The following applications will be revised and reviewed by VSAC at a later date:

1. Project Title: Analyzing the Correlation between County Level Capital Funding for Smoking Prevention Interventions and Infant Mortality Rates in California
Principal Investigator: Sunday Oyewole, MPH, University of Phoenix
Project Type: New Project
Data Requested: 2009-2012 Birth Cohort Files
2. Project Title: Evaluating a Pilot Mobile Health Program
Principal Investigator: Sasigant O’Neil, Mathematica Policy Research
Project Type: New Project
Data Requested: 2012-2016 Birth Files
3. Project Title: Language Development in Infants
Principal Investigator: Toben Mintz, Ph.D., University of Southern California
Project Type: Continuing Project
Data Requested: 5/11/2011 – 8/1/2016 Birth Files
4. Project Title: The California Maternal Data Center: Establishing a Statewide Data Center for Use in Rapid-Cycle Maternity Care Improvement Projects
Principal Investigator: Jeffrey Gould, MD, MPH, Stanford University
Project Type: Continuing Project
Data Requested: 2011-2021 Birth Files, 2011-2021 Fetal Death Files

ATTACHMENT 2 – CONSENT CALENDAR: OSHPD DATA REQUESTS

1. **Project Title:** California Maternal Child and Adolescent Health Report
Principal Investigator: Lisa Nicholas, MD, University of California, Los Angeles
Project Type: New Project
Data Requested: 2010-2012 Linked PDD/ED/AS/Birth Cohort

Discussion: None

A **MOTION** was made by Sun Lee and **SECONDED** by Linda Remy to recommend approval. Sun Lee, Emily Putnam-Hornstein, Linda Remy and Ninez Ponce voted aye to unanimously recommend to the State Registrar to approve the use of the data as described in the protocol.

ATTACHMENT 3 – DISCUSSION ITEMS – NEW BUSINESS

1. **Project Title:** Evaluating a Pilot Mobile Health Program
Principal Investigator: Sasigant O'Neil, Mathematica Policy Research
Project Type: New Project
Data Requested: 2012-2016 Birth Files

Discussion: None. This application was not reviewed due to the need for additional information requested from the applicant.

2. **Project Title:** Maternal Smoking During Pregnancy, Maternal Complications, Birth Outcomes and Infant Mortality; A Seven-Year Retrospective from California Birth Files: 2007-2013
Principal Investigator: Anura Ratnasiri, California Department of Health Care Services
Project Type: New Project
Data Requested: 2010-2015 Confidential Infant Reconciliation, 2010-2015 Birth Files, 2010-2015 Fetal Death Files, 2010-2015 Multiple Cause of Death Files, 2014-2015 Death Files

Discussion: None. This application was not reviewed due to the need for additional information requested from the applicant.

3. **Project Title:** Effect of Agricultural Pesticides on Adverse Birth Outcomes
Principal Investigator: Ashley Larsen, PhD, University of California, Santa Barbara
Project Type: Continuing Project

Data Requested: 2012-2013 Birth Files

Discussion: The Committee discussed concerns that the Committee for the Protection of Human Subjects (CPHS) approval is pending. It was explained that CPHS will now issue approval after VSAC approval was issued. The data will not be released without CPHS approval.

A **MOTION** was made by Ninez Ponce and **SECONDED** by Sun Lee to recommend approval. Sun Lee, Ninez Ponce, Emily Putnam-Hornstein, and Linda Remy voted aye to recommend to the State Registrar to approve the use of the data as described in the protocol subject to receiving CPHS approval.

4. **Project Title:** Trends in Regional Specialty Care Hospitalizations for Children in California

Principal Investigator: Lee Sanders, MD, Stanford University

Project Type: Continuing Project

Data Requested: 2012-2014 Death Files, 2012-2013 PDD/Linked Death Files, 2015 PDD File

Discussion: None

A **MOTION** was made by Linda Remy and **SECONDED** by Sun Lee to recommend approval. Linda Remy, Ninez Ponce, Emily Putnam-Hornstein, and Sun Lee voted aye to recommend to the State Registrar to approve the use of the data as described in the protocol.

5. **Project Title:** Drinking Water Quality and Infant Health

Principal Investigator: Heather Royer, University of California Santa Barbara

Project Type: Continuing Project

Data Requested: 2013 Birth File, 2002-2012 Birth Cohort Files

Discussion: Clarification of the physical location of Southwestern University is needed. Southwestern University needs to be listed in the Data Access Section of the research application. The need for the Father's Date of Birth as a necessary variable was discussed. The linkage and how it relates to the study was also addressed. It was determined that the data set linkage was appropriate. A determination to allow both this variable and the Father's Age was made. Data will not be released without CPHS approval. The applicant must also submit CPHS approval letter before the data can be released.

A **MOTION** was made by Ninez Ponce and **SECONDED** by Linda Remy to recommend approval with stipulations that the Research application and

CPHS protocol provide clarification on Southwestern University's role in the project data storage and access. If data will be stored and/or accessed at Southwestern University, a signed IPSR must be submitted. Linda Remy, Emily Putnam-Hornstein, Ninez Ponce, and Sun Lee voted aye to unanimously recommend to the State Registrar to approve the use of the data as described in the protocol subject to receiving CPHS approval.

6. **Project Title:** Using Population-Based Data Sets to Generate and Test New Hypotheses for Investigating Preterm Births and Related Adverse Conditions in California

Principal Investigator: Gary Shaw, PhD, Stanford University

Project Type: Continuing Project

Data Requested: 1960-2012 Birth Files, 1970-2010 Fetal Death Files, 2012 Linked PDD/EDD/AS/Death File

Discussion: Signed Information Privacy and Security Requirements (IPSR) forms are pending. Data will not be released prior to the receipt of IPSRs.

A **MOTION** was made by Linda Remy and **SECONDED** by Sun Lee to recommend approval. Ninez Ponce, Linda Remy, Emily Putnam-Hornstein, and Sun Lee voted aye to recommend to the State Registrar to approve the use of the data as described in the protocol.

7. **Project Title:** San Francisco Mammography Registry: A Research Resource

Principal Investigator: Karla Kerlikowske, MD, University of California San Francisco

Project Type: New Project

Data Requested: 2014-2015 Death Files

Discussion: CDPH staff to contact Principal Investigator (PI); requestor is not allowed to release data files to an outside contractor. The PI needs to revise and re-submit Research application.

The protocol states, "The BCSC was required to share data with outside researchers. However, beginning with the sixth year of our grant (i.e., beginning August 2016) it will no longer be a requirement." The Research application and CPHS protocol must be revised to include a statement clarifying that the pooled data file will not be re-shared with others.

A separate Research application needs be submitted by the entity that will house the pooled registry (Statistical Coordinating Center). This application must include who will create, house, store and maintain the pooled database. It should also include who is responsible for the database, and

how the applicant will ensure that anyone accessing the data goes through the appropriate approval process. Anyone requesting this information must be listed as a co-PI or a contractor in this application to receive the vital records data.

The Committee also recommended that both applications come back for review and recommendation.

A **MOTION** was made by Sun Lee and **SECONDED** by Linda Remy to recommend not approving the project. Sun Lee, Emily Putnam-Hornstein, Ninez Ponce, and Linda Remy voted aye to unanimously recommend that the State Registrar not approve the use of the data as described in the protocol. The original Research application needs to be revised to include those who will have access to the pooled data. A second Research application needs to be submitted by the entity that will house the pooled registry (Statistical Coordinating Center). Both applications need VSAC review and recommendation prior to the release of the data.

8. **Project Title:** The California Maternal Data Center: Establishing a Statewide Data Center for Use in Rapid-Cycle Maternity Care Improvement Projects

Principal Investigator: Jeffrey Gould, MD, Stanford University

Project Type: Continuing Project

Data Requested: 2011-2021 Birth Files, 2011-2021 Fetal Death Files

Discussion: Signed IPSRs are pending. Data will not be released prior to the receipt of IPSRs.

A **MOTION** was made by Linda Remy and **SECONDED** by Ninez Ponce to recommend approval with the stipulation that the application be reviewed again within a three-year period (unless there are material changes prior to that time, which would require the applicant immediately notify CDPH and VSAC). Ninez Ponce, Sun Lee, Emily Putnam-Hornstein, and Linda Remy voted aye to recommend to the State Registrar to approve the use of the data with the stipulation that annual CPHS approval should be maintained and that the application is to be reviewed within a three-year period.

9. **Principal Investigator:** Shabbir Ahmad, California Department of Public Health (CDPH), Maternal Child and Adolescent Health

Project Type: Continuing Project

Data Requested: 2015 Birth File, 2015 Death File

Discussion: The contractor needs to be listed in the Data Access section of the application, and needs to complete and submit an IPSR. The PI needs to

submit a CPHS Exempt for Research letter also needs to be submitted to CDPH. The Statement of Intended Use is vague. The PI needs to revise it to include a list all of the datasets and population-based data that will be linked to the vital statistics data.

A **MOTION** was made by Sun Lee and **SECONDED** by Linda Remy to recommend approval with the stipulation that the application needs to include a detailed description of all the data sets that will be linked to the vital statistics data. The contractor needs to be listed in the Data Access section and also needs to submit an IPSR. Ninez Ponce, Linda Remy, Emily Putnam-Hornstein, and Sun Lee voted aye to recommend to the State Registrar to approve the use of the data as described in the protocol with the following stipulations: The Research application also needs to be revised and resubmitted to include a list of linking data and population-based data sets that will be linked to the vital statistics data. A CPHS Exempt for Research letter also needs to be submitted to CDPH.

10. **Principal Investigator:** Shabbir Ahmad, California Department of Public Health (CDPH), Maternal Child and Adolescent Health
Project Type: Continuing Project
Data Requested: 2013 Birth Cohort File

Discussion: The Statement of Intended Use is vague. The PI needs to revise it to include a list all of the datasets and population-based data that will be linked to the vital statistics data.

A **MOTION** was made by Sun Lee and **SECONDED** by Linda Remy to recommend approval with the stipulation that application needs to include a detailed description of all the data sets that that will be linked to vital statistics data. Ninez Ponce, Linda Remy, Emily Putnam-Hornstein and Sun Lee voted aye to recommend to the State Registrar to approve the use of the data as described in the protocol with the stipulation that the application is revised and resubmitted to include a list of linking data sets and population-based data sets that will be linked to the vital statistics data.

A **MOTION** was made by Linda Remy and **SECONDED** by Sun Lee to call for the reconsideration of the motion for the prior item heard. Ninez Ponce, Linda Remy, Emily Putnam-Hornstein and Sun Lee voted aye to reconsider the motion for the prior item.

ADDITIONAL DISCUSSION TOPICS:

The VSAC/CPHS process will be discussed at the next meeting.

MEETING ADJOURNMENT:

A **MOTION** was made by Sun Lee and **SECONDED** by Linda Remy to adjourn the meeting. Linda Remy, Sun Lee, Emily Putnam-Hornstein, and Ninez Ponce voted aye to unanimously recommend to approve adjourning the meeting.

The meeting was adjourned at 10:18 a.m.